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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/722,867	11/27/2000	Maria Grazia Pau	4626US	4248
24247	7590	02/22/2006	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			HILL, MYRON G	
			ART UNIT	PAPER NUMBER
			1648	
DATE MAILED: 02/22/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/722,867	PAU ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36,38-40,42-45 and 50-52 is/are pending in the application.
- 4a) Of the above claim(s) 36,38,39,45 and 52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40,42-44,50 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>see action</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This action is in response to the paper filed 28 November 2005.

Claims 40, 42-44 and 46-51 are under consideration.

Information Disclosure Statement

Signed and initialed copies of the IDS papers filed 10/31/2005, 12/29/2005, and 1/12/2006 are enclosed.

Rejections Withdrawn

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 40, 42-44, 50, and 51 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what the metes and bounds required for "part" and "partial" are (what is the level of infectivity or purification).

Applicant has amended the claims and the rejection is withdrawn.

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Claim Rejections - 35 USC § 102

Claims 40 and 42 were rejected under 35 U.S.C. 102(b) as being anticipated by Merton *et al.*

Applicant has amended the claims and the rejection is withdrawn.

Double Patenting

Claim 1 of this application conflicts with claim 1 of Application No. 09/449,852. Applicant canceled claim 1 and the rejection is withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 103

Claims 40, 42-44, 50, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over and Merton *et al.* in view of Paul RW *et al.* (Paul).

The claims are drawn to a method of concentrating cell cleared influenza virus containing supernatant under low shear conditions. The dependent claims add cutoff values for the filtration. Applicant has moved the limitation of claim 41 (hollow fiber) to claim 40 and canceled 41 and 46-49.

Applicant argues that Paul teaches retroviral vectors in the paper and that low infectious virus recovery is obtained (p610), extensive experimentation would be needed and thus burdensome, expense is not motivation to combine, no expectation of success, and an inventive step is required to provide the claimed method.

Applicant's arguments have been full considered and not found persuasive.

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While Paul shows initial low infectious recovery on page 610, further experiments show higher levels of recovery. It is routine to optimize parameters as shown by Paul and routine optimization is not undue burden. The method is generally applicable as noted by Paul and mentioned by applicant. The art is related in that it deals with virus purification. Paul is not relied on to show influenza infectivity. The rejection is not based on one reference.

Applicant has provided no unexpected results. Merton *et al.* and one of ordinary skill in the art as previously stated would know about influenza virus and infectivity.

Thus, the rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Myron G. Hill
Patent Examiner
20 February 2006



JAMES HOUSEL 2/21/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600